

(iii) The Director and Deputy Director, Office of Compliance, CDRH.

(iv) The Director and Deputy Director, Division of Compliance Programs, CDRH.

(v) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

(11)(i) The Director and Deputy Directors, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Management, CVM.

(iii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iv) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(v) The Chief, Case Guidance Branch, Division of Compliance, Office of Surveillance and Compliance, CVM.

(12)(i) The Director and Deputy Director, National Center for Toxicological Research (NCTR).

(ii) The Director, Office of Research Support, NCTR.

(13)(i) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Management, Epidemiology and Biostatistics, Compliance, Drug Evaluation I, Drug Evaluation II, Research Resources, Generic Drugs, and Over-the-Counter Drug Evaluation, CDER.

(iii) The Chief and Freedom of Information Officers, Freedom of Information Staff, Office of Management, CDER.

(iv) The Director, Division of Management and Budget, Office of Management, CDER.

(v) The Directors of the Divisions of Drug Labeling Compliance, Drug Quality Evaluation, Manufacturing and Product Quality, and Scientific Investigations, Office of Compliance, CDER.

(14)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) The Director, St. Louis Branch.

(iv) The Director, New York Laboratory Division, Northeast Region.

(v) The Director, Southeast Regional Laboratory, Southeast Region.

(vi) The Director, National Forensic Chemistry Center.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

(1) Deputy Commissioners.

(2) The Associate and Deputy Associate Commissioners.

(3) The Director, Office of Human Resources Management, Office of Management.

(c) The Chief, Regulations Editorial Section and his/her alternates, Regulations Policy and Management Staff, Office of Policy, Office of the Commissioner are authorized to certify true copies of FEDERAL REGISTER documents.

[50 FR 4858, Feb. 4, 1985, as amended at 58 FR 17095, Apr. 1, 1993; 60 FR 26826, May 19, 1995; 61 FR 9639, Mar. 11, 1996]

§ 5.23 Disclosure of official records.

(a) The following officials are authorized to make determinations to disclose official records and information under part 20 of this chapter, except that only the officials listed in paragraph (a)(1) of this section may disclose official records and information under §§ 20.82 and 20.85 of this chapter, and only officials listed in paragraph (a)(10) of this section may disclose information under § 20.89(c) of this chapter.

(1) Associate and Deputy Associate Commissioners.

(2)(i) The Director, Office of the Executive Assistant.

(ii) The Director, Executive Secretariat.

(iii) The Director, Program Management Staff.

(3) Executive Officer, Office of the Commissioner.

(4) The Chief, Dockets Management Branch, Division of Management Systems and Policy, Office of Management and Operations.

(5) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(6) Regional Food and Drug Directors and District Directors.

(7) Director, Winchester Engineering and Analytical Center.

(8) Chiefs of branches Field/District Offices and Centers.

(9) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(10)(i) The Associate Commissioner for Regulatory Affairs, Deputy Associate Commissioner for Regulatory Affairs, and Director, Office of Enforcement, FDA.

(ii) The Director, Deputy Director, and Associate Director for Policy Coordination and Public Affairs, Center for Biologics Evaluation and Research (CBER), and Director, Division of Congressional and Public Affairs, CBER.

(iii) The Director, Deputy Directors, and Associate Director for Science and Medical Affairs, Center for Drug Evaluation and Research (CDER).

(iv) The Director and Deputy Director for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(v) The Director, Center for Food Safety and Applied Nutrition (CFSAN), and Deputy Director for Systems and Support, CFSAN.

(vi) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(vii) The Director, Deputy Director, and Associate Director for Scientific Coordination, National Center for Toxicological Research (NCTR).

(b) The Chief, Drug Listing Branch, Division of Drug Labeling Compliance, Office of Compliance, Center for Drug Evaluation and Research (CDER), is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records:

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(3) The Director, Division of Product Surveillance, Office of Compliance and Surveillance, CDRH.

(4) The Chief, Device Registration and Listing Branch, Division of Product Surveillance, Office of Compliance and Surveillance, CDRH.

(d) The Chief of the Records Section of the Administrative Services Branch,

Division of Management Services, Office of Management and Operations, is authorized to sign affidavits regarding the presence or absence of records in the files of that section.

(e) The Director and Deputy Director, Division of Product Certification, Office of Biological Product Review, Center for Biologics Evaluation and Research, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments.

[43 FR 29286, July 7, 1978, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 51 FR 11428, Apr. 3, 1986; 54 FR 8315, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 59 FR 37419, July 22, 1994]

§ 5.24 Authority relating to technology transfer.

(a) The Associate Commissioner for Regulatory Affairs is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under sections 11(c)(5) (A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended.

(b) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*), as amended, and Executive Order 12591 of April 10, 1987, except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(29) of this part, as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner of Food and Drugs to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with section